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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----X
JASON COLEMAN,

Plaintiff,

- against -

STATE SUPREME COURT, et al.,

Defendants.
-----X

09 Civ. 1072 (VM)

DECISION AND ORDER

VICTOR MARRERO, United States District Judge.

I. BACKGROUND

Plaintiff Jason Coleman ("Coleman") brought this action alleging violations of his rights under the federal and New York State Constitutions, as well as New York common law claims, arising from his placement in a program of assisted outpatient treatment with a requirement to self-administer psychotropic drugs or accept the administration of such drugs, pursuant to a court order under Section 9.60 of the New York Mental Hygiene Law ("§ 9.60").

By Order dated February 25, 2010, Magistrate Judge Frank Maas, to whom this matter had been referred for supervision of pretrial proceedings, issued a Report and Recommendation (the "Report"), a copy of which is attached and incorporated herein, finding that § 9.60 does not violate the federal or New York State Constitutions and that the Court lacks subject matter jurisdiction over Coleman's claims against the FDA, and

recommending that defendants' motions to dismiss the complaint be granted as to Coleman's federal and New York State constitutional claims. The Report also recommends that the Court dismiss Coleman's products liability claims against Eli Lilly and Company as implausible. The Report further recommends that the Court not exercise pendent jurisdiction over Coleman's remaining state law causes of action and that those claims be dismissed without prejudice. Finally, the Report recommends that Coleman's motion for reconsideration of the Court's denial of his motion for a judgment by default against defendant State Supreme Court Part of Mental Health Hygiene ("MHH")¹ be denied. Coleman has filed no objections to the Report though the deadline for such submission was March 15, 2010. For the reasons stated below, the Court adopts the recommendations of the Report in their entirety.

II. STANDARD OF REVIEW

A district court evaluating a magistrate judge's report may adopt those portions of the report to which no "specific, written objection" is made, as long as the factual and legal bases supporting the findings and conclusions set forth in those sections are not clearly erroneous or contrary to law. Fed. R. Civ. P. 72(b); see also Thomas v. Arn, 474 U.S. 140,

¹ MHH has not appeared in this action because, as the Court found in denying Coleman's motion for default judgment, MHH was not properly served.

149 (1985); Greene v. WCI Holding Corp., 956 F. Supp. 509, 513 (S.D.N.Y. 1997). "Where a party makes a 'specific written objection ... after being served with a copy of the [magistrate judge's] recommended disposition,' however, the district court is required to make a de novo determination regarding those parts of the report." Cespedes v. Coughlin, 956 F. Supp. 454, 463 (S.D.N.Y. 1997) (citing United States v. Raddatz, 447 U.S. 667, 676 (1980)); Fed. R. Civ. P. 72(b). The Court is not required to review any portion of a magistrate judge's report that is not the subject of an objection. See Thomas, 474 U.S. at 149. A district judge may accept, set aside, or modify, in whole or in part, the findings and recommendations of the magistrate judge as to such matters. See Fed. R. Civ. P. 72(b); DeLuca v. Lord, 858 F. Supp. 1330, 1345 (S.D.N.Y. 1994).

III. DISCUSSION

Having conducted a full review of the full factual record in this litigation, including the pleadings, and the parties' respective papers submitted in connection with the underlying motions and in this proceeding, as well as the Report and applicable legal authorities, the Court concludes that the findings, reasoning, and legal support for the recommendations made in Report are not clearly erroneous or contrary to applicable law. Accordingly, for substantially the reasons

set forth in the Report the Court adopts the Report's factual and legal analyses and determinations, as well as its substantive recommendations, in their entirety as the Court's ruling on defendants' underlying motions to dismiss Coleman's complaint.

IV. ORDER

For the reasons discussed above, it is hereby

ORDERED that the Report and Recommendation of Magistrate Judge Frank Maas dated February 25, 2010 (Docket No. 55) is adopted in its entirety, and the motions of defendants City of New York (Docket No. 14), Food and Drug Administration (Docket No. 39), Eli Lilly and Company (Docket No. 42) and Ortho-McNeil-Janssen Pharmaceuticals, Inc. (Docket No. 50), to dismiss the complaint of plaintiff Jason Coleman ("Coleman") are GRANTED in full; and that the motion of defendant Bellevue Hospital Center (Docket No. 36) is GRANTED in respect of Coleman's constitutional claims; and it is further

ORDERED that Coleman's motion for reconsideration of the Court's denial of his application for entry of a default judgment against defendant State Supreme Court Part of Mental Health Hygiene (Docket No. 48) is DENIED; and it is finally

ORDERED that Coleman's remaining state law claims are dismissed without prejudice.

The Clerk of Court is directed to withdraw any pending motions and to close this case.

SO ORDERED.

Dated: NEW YORK, NEW YORK
17 March 2010

A handwritten signature in black ink, appearing to read 'Victor Marrero', is written over a horizontal line.

VICTOR MARRERO
U.S.D.J.

JASON COLEMAN,
v.
(STATE) SUPREME COURT, PART OF
MENTAL HEALTH HYGIENE, FOOD AND
DRUG ADMINISTRATION (FDA),
JANSSEN, ELI LILLY AND COMPANY,
ST. LUKE'S HOSPITAL, BELLEVUE
HOSPITAL CENTER and CITY OF NEW YORK.

09 Civ 1072

Report and Recommendation of
Magistrate Judge Frank Maas
dated February 25, 2010

Attachment to the Court's
Decision and Order
dated March 17, 2010

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

USDC SDNY
DOCUMENT
ELECTRONICALLY FILED
DOC #:
DATE FILED: 2/25/10

JASON COLEMAN,

Plaintiff,

- against -

(STATE) SUPREME COURT, PART OF
MENTAL HEALTH HYGIENE, FOOD
AND DRUG ADMINISTRATION (FDA),
JANSSEN, ELI LILLY AND COMPANY,
ST. LUKE'S HOSPITAL, BELLEVUE
HOSPITAL CENTER, and
CITY OF NEW YORK,

Defendants.

**REPORT AND
RECOMMENDATION
TO THE HONORABLE
VICTOR MARRERO**

09 Civ. 1072 (VM)(FM)

2010

FRANK MAAS, United States Magistrate Judge.

In this case, pro se plaintiff Jason Coleman ("Coleman"), who has been diagnosed as a paranoid schizophrenic, challenges the constitutionality of his placement in a program of assisted outpatient treatment ("AOT") pursuant to a court order issued under Section 9.60 of the New York Mental Hygiene Law ("Section 9.60"), more commonly known as "Kendra's Law." Coleman also contends that he experienced harmful side effects from the antipsychotic medications the court order required him to take. He seeks to recover a total of \$245 million in damages from seven defendants: the City of New York ("City"), the Food and Drug Administration ("FDA"), Eli Lilly and

Company (“Lilly”), Ortho-McNeil-Janssen Pharmaceuticals, Inc. (“Ortho”),¹ Saint Luke’s Hospital (“St. Luke’s”), Bellevue Hospital Center (“Bellevue”), and the Mental Hygiene Part (“MHP”) of the New York State Supreme Court.² (See Docket No. 1 (Compl. ¶¶ IV-V & Attach. ¶¶ 3(5), 5)).

The City, Bellevue, and Lilly each have moved to dismiss Coleman’s complaint for failure to state a claim pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. (Docket Nos. 14, 36, 42). Additionally, the FDA has moved to dismiss the complaint for lack of subject matter jurisdiction pursuant to Rule 12(b)(1), and Ortho has moved for judgment on the pleadings pursuant to Rule 12(c). (Docket Nos. 39, 50). Finally, Coleman seeks reconsideration of this Court’s prior denial of his motion for a default judgment against MHP and Bellevue. (Docket No. 48). (St. Luke’s has not filed any motion.)

For the reasons set forth below, I recommend that the motions filed by the defendants be granted in part and denied in part, and that Coleman’s motion for reconsideration be denied. Additionally, because this disposition means that only state law claims will remain in this suit, I recommend that those claims be dismissed without prejudice.

¹ In his complaint, Coleman incorrectly identifies this defendant as “Janssen.” (See Ortho Mem. at 1).

² The MHP of the State Supreme Court is named in the complaint as the State Supreme Court, Part of Mental Health Hygiene.

I. Background

A. Kendra's Law

In 1999, the New York State legislature enacted Section 9.60 following the tragic death of Kendra Webdale, who was pushed in front of a subway train by a man diagnosed with paranoid schizophrenia who had failed to take his medications. See N.Y.S. Senate Mem. in Supp. of Kendra's Law, reproduced in 1999 N.Y. Sess. Laws 1822, 1825 (McKinney); In re K.L., 1 N.Y.3d 362, 366 (2004). The legislature subsequently extended the statute, with certain modifications, for five additional years past its original June 30, 2005 sunset date. See 2005 N.Y. Sess. Laws 137, 158 (McKinney). Section 9.60 authorizes the New York courts to require that a patient "self-administer psychotropic drugs or accept the administration of such drugs by authorized personnel." N.Y. Mental Health Law ("MHL") § 9.60(j)(4). This outpatient program has a number of components, including case management or case coordination services, medication, substance abuse counseling and testing, and therapy. See id. § 9.60(a)(1).

For a court to order AOT, an eligible petitioner – who may be a family member, director of a hospital where the patient is hospitalized, parole officer, social worker, psychologist, psychiatrist, or county social services officer – must show by clear and convincing evidence that seven statutory criteria have been met. Id. § 9.60(e)(1), (j)(3). These criteria are that the individual:

- is eighteen years of age or older;

- is suffering from a mental illness;
- is unlikely to survive safely in the community without supervision;
- has a history of noncompliance with treatment for mental illness that prior to the filing of the petition has:
 - been a significant factor in necessitating hospitalization at least twice within the last thirty-six months, or
 - resulted within the last forty-eight months in one or more acts of serious violent behavior toward himself or others, or threats of, or attempts at, serious physical harm to himself or others;
- is, as a result of mental illness, unlikely to participate voluntarily in outpatient treatment that would enable him to live safely in the community;
- is in need of AOT to prevent a relapse or deterioration that would be likely to result in serious harm to himself or others; and
- is likely to benefit from AOT.

Id. § 9.60(c). The petition also must include an affirmation from a physician (other than the petitioner) that establishes that the physician has examined the patient and recommends AOT, or has not been able to examine him but has reason to suspect that he meets the criteria for it to be imposed. Id. § 9.60(e)(3). If the patient refuses to consent to an examination by a physician and the court finds reasonable cause to believe that the allegations in the petition are true, the court may order law enforcement officials to take him into custody and transport him to a hospital where he may be held for a maximum of twenty-four hours for an examination. Id. § 9.60(h)(3).

Absent good cause shown, a hearing must be held within three days of the state court's receipt of the petition. Id. § 9.60(h)(1). The individual has the right to be represented at the hearing and all other stages of the proceeding by the New York Mental Hygiene Legal Service³ or private counsel. Id. § 9.60(g). At the hearing, a physician who has personally examined the subject of the hearing must testify in person. Id. § 9.60(h)(2). During that testimony, the physician must identify the facts supporting the allegation that the patient meets each of the criteria for AOT and that such treatment is "the least restrictive alternative." Id. § 9.60(h)(4). The physician also must detail the recommended program of AOT and the rationale for that treatment. Id. The physician must further "describe the types or classes of medication which should be authorized, . . . describe the beneficial and detrimental physical and mental effects of such medication, and . . . recommend whether such medication should be self-administered or administered by authorized personnel." Id. Section 9.60 also permits the patient to present evidence, call witnesses, and cross-examine adverse witnesses. Id. § 9.60(h)(5).

Assuming that an individual meets the statutory criteria, the court's ability to order AOT is further contingent upon the submission of a written treatment plan developed by an appointed physician in consultation with the patient, the patient's

³ Each judicial department in the State has a Mental Hygiene Legal Service to provide legal assistance to persons alleged to be in need of mental health care and their families. See MHL §§ 47.01, 47.03.

treating physician, and, upon the patient's request, a significant other, such as a close friend or relative. Id. § 9.60(i)(1)-(2).

The period of any initial AOT order may not exceed six months. Id. § 9.60(j)(2). Thereafter, renewal of the AOT order may be sought for periods of up to one year. Id. § 9.60(k). An AOT order issued by the court may be reviewed in the same manner as an order directing that a person be involuntarily detained in a mental health facility. Id. § 9.60(m). Thus, the patient (or a relative or friend acting on his behalf) may seek review within thirty days, in which event a justice other than the one entering the AOT order must "cause a jury to be summoned." Id. § 9.35. Unless waived, the jury must try the question of the patient's mental illness (and presumably the need for AOT). Id.

Finally, when a physician determines that a patient has failed or refused to comply with AOT despite efforts to induce compliance, and that the patient may require involuntary inpatient treatment, he may ask the director of the hospital providing the AOT, or the director of community services of a local governmental unit, to direct that the patient be transported to a hospital and held for up to seventy-two hours to evaluate whether the patient should be committed as an inpatient. Id. § 9.60(n). Police officers also may be directed to take the patient to an appropriate hospital for evaluation. Id.

Significantly, Section 9.60 provides that the "[f]ailure to comply with an order of assisted outpatient treatment shall not be grounds for involuntary civil

commitment or a finding of contempt of court.” Id. Thus, a physician cannot commit a patient merely because he has failed to comply with AOT. The physician may, however, consider a patient’s refusal to take required medications or comply with alcohol or drug testing, or the failure of such tests, in determining whether further examination is necessary. Id.

B. Coleman’s Psychiatric History and Treatment⁴

Coleman was diagnosed with paranoid schizophrenia in late 2004. (See Compl. ¶¶ III(A)-(B); Decl. of Ass’t Corp. Counsel Jacqueline Hui, dated Apr. 16, 2009 (“Hui Decl. I”), Ex. A; Affirm. of Scott Soloway, M.D., dated July 26, 2006, ¶¶ 4, 7). As a consequence of his failure to comply with his treatment, he was hospitalized at St. Luke’s from October 4 to 27, 2004, July 31 to August 23, 2005, and May 3 to June 1, 2006. (Id. ¶ 6).

On August 16, 2006, the director of the AOT program in Manhattan successfully petitioned the MHP for an order requiring Coleman to participate in AOT for six months. (See Hui Decl. I Ex. A). The petition was based on Coleman’s history of paranoid schizophrenia and hospitalizations for treatment noncompliance. (Id.). Pursuant to the order, Coleman was required to participate in AOT at Bellevue, which is part of the

⁴ Three of the defendants served Coleman with the notice required by Local Civil Rule 12.1, which warns him that the Court may rely on materials beyond his complaint. (See Docket Nos. 41, 44, 49). Moreover, Coleman himself has submitted additional materials in opposition to the defense motions. (See Docket Nos. 46, 47, 52, 54). For these reasons, the factual summary that follows relies on both Coleman’s complaint and the additional materials submitted by the parties.

New York City Health and Hospitals Corporation. (See Compl. ¶ III(C); Compl. Attach. ¶ 3(1); Docket No. 31 (Decl. of Jacqueline Hui, Esq., dated June 2, 2009 (“Hui Decl. II”), ¶ 4)).

On February 13, 2007, based on the AOT director’s renewed petition, the MHP ordered Coleman to participate in AOT for an additional six months. (Hui Decl. I Ex. B). The MHP issued additional orders requiring Coleman to participate in AOT for six-month intervals on August 14, 2007, February 8, 2008, and August 5, 2008. (Id. Exs. C-E).

On February 16, 2009, Coleman “graduated” from the AOT program at Bellevue because of his compliance with his treatment plan. (Id. Ex. F). Despite the fact that he no longer is required to participate in AOT, Coleman has brought this action in an effort to recover money damages. (Compl. ¶ V).

C. Complaint

In his complaint, Coleman contends that it is his right “as a U.S. citizen not to take meds if he doesn’t want to.” (Id. Attach. ¶ 3(1)). Coleman asserts that he nevertheless was “forced to take medication and attend a program by [MHP]” though he had not “broken any laws [or] done anything to [him]self or anyone else.” (Id. ¶ III(C)). He complains that the medication caused him to develop a heart problem and nausea and made him feel worse, not better. (Id. ¶¶ III(C), IV).

Coleman further contends that the MHP violated his civil rights and the “Patient Bill of Rights”⁵ by directing that he take medication and attend a program without affording him a jury trial, although he was neither incapacitated nor subject to a guardianship. (Compl. Attach. ¶ 3(1)). Coleman alleges that he also was not permitted to see a health care provider other than the one appointed by MHP. (Id.).

Coleman alleges that the FDA acted negligently by permitting Ortho and Lilly to “put harmful medication on [the] market.” (Id. at ¶ 3(2)). He similarly contends that these medications, which are intended to help people with mental illness, “only make . . . things worse (Alzheimer’s Disease etc.).” (Id.). According to Coleman, the FDA “should be paying attention to all medication.” (Id.).

With respect to Ortho, the manufacturer of Haldol and Risperdal, two of the antipsychotic medications that Coleman’s physician at St. Luke’s allegedly prescribed, Coleman maintains that “[t]he medication has too many side effects,” including nausea, heart failure, Alzheimer’s Disease, and “decreased sexual ability.” (Compl. ¶ V & Attach. ¶ 3(3)). He also notes that women who are using the medication allegedly cannot breast feed. (Id.). For these reasons, he opines that the medications “do more harm than good” and “shouldn’t even be on the market.” (Id.).

⁵ Section 2803(1)(g) of the New York Public Health Law requires every general hospital in the state to make available to their patients a statement of patient rights and responsibilities promulgated by the Commissioner of Health.

Coleman similarly claims that Lilly was negligent because its antipsychotic medication, Zyprexa, has side effects comparable to those associated with Risperdal and Haldol. (Compl. Attach. ¶ 3(4)). Coleman notes that he is further “concerned” that “[p]eople are being forced to take these meds [which] are not working as well as they should.” (Id.).

Coleman also alleges that he has “not been the same” since he began receiving treatment at St. Luke’s in 2004, and that he has experienced “problems vomiting, concentrating,[and] sleeping,” hears “voices occasionally in his head,” and has “heart problems.”⁶ (Id. ¶ 3(5)).

Finally, Coleman asserts that if he failed to attend the AOT program or take his medications, he would be arrested, “no matter where he is or what he is doing,” and taken to see a psychiatrist. (Id. Attach. ¶ 3(6&7)). He further complains that in such instances he has been charged for the use of ambulance services. (Id.).

Liberal construed, Coleman’s complaint can be read to allege that (1) the MHP, the City, and Bellevue violated his substantive and procedural due process rights under the New York and United States constitutions; (2) the FDA was negligent in allowing certain antipsychotic medications to be sold; (3) Ortho and Lilly failed to warn

⁶ Coleman claims that St. Luke’s “prescribed mental health medication without a diagnosis” and kept him against his will. (Id.). According to Coleman, St. Luke’s further failed to provide any treatment for his heart problems and violated the Patient Bill of Rights. (Id.).

him adequately about the side effects of their drugs; and (4) Bellevue and St. Luke's failed to inform him of the side effects of the drugs their physicians prescribed.

II. Standard of Review

A. Motions to Dismiss

Under Rule 12(b)(1) of the Federal Rules of Civil Procedure, a complaint must be dismissed if a court lacks subject matter jurisdiction over the claims asserted. In resolving the issue of subject matter jurisdiction, a court is not limited to the face of the complaint and may consider evidence outside the pleadings. Phifer v. City of New York, 289 F.3d 49, 55 (2d Cir. 2002). The plaintiff has the burden of proving by a preponderance of the evidence that subject matter jurisdiction exists. Id. (citing Makarova v. United States, 201 F.3d 110, 113 (2d Cir. 2000)); Shipping Fin. Servs. Corp. v. Drakos, 140 F.3d 129, 131 (2d Cir. 1998) ("jurisdiction must be shown affirmatively, and that showing is not made by drawing from the pleadings inferences favorable to the party asserting it").

Under Rule 12(b)(6) of the Federal Rules, a court must dismiss a complaint that fails to state a claim upon which relief can be granted. In deciding a motion under Rule 12(b)(6), the Court must accept as true all factual allegations made in the complaint and draw all reasonable inferences in favor of the plaintiff. Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit, 507 U.S. 163, 164 (1993); Newman & Schwartz v. Asplundh Tree Expert Co., 102 F.3d 660, 662 (2d Cir. 1996). The first of

these precepts, however, is inapplicable to legal conclusions couched as factual allegations, which the Court is “not bound to accept as true.” Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007). As the Supreme Court has explained, the ultimate issue to be decided under Rule 12(b)(6) is whether the plaintiff’s claims are “plausible.” Id. at 556. Determining whether the allegations of a complaint nudge a plaintiff’s claims across the line from “conceivable to plausible” requires a court to “draw on its judicial experience and common sense.” Ashcroft v. Iqbal, ___ U.S. ___, 129 S. Ct. 1937, 1950-51 (2009).

B. Motion for Judgment on the Pleadings

Under Rule 12(c), judgment on the pleadings is appropriate when the material facts are undisputed and a party is entitled to judgment as a matter of law based on the contents of the pleadings. See, e.g., Sellers v. M.C. Floor Crafters, Inc., 842 F.2d 639, 642 (2d Cir. 1988); Guy v. Astrue, 615 F. Supp. 2d 143, 158 (S.D.N.Y. 2009). “In deciding a Rule 12(c) motion, [courts] apply the same standard as that applicable to a motion under Rule 12(b)(6), accepting the allegations contained in the complaint as true and drawing all reasonable inferences in favor of the nonmoving party.” Ziemba v. Wezner, 366 F.3d 161, 163 (2d Cir. 2004) (quoting Burnette v. Carothers, 192 F.3d 52, 56 (2d Cir. 1999)).

C. Pro Se Plaintiffs

Where, as here, a plaintiff is proceeding pro se, the Court is obligated to “read his supporting papers liberally, and . . . interpret them to raise the strongest arguments that they suggest.” Burgos v. Hopkins, 14 F.3d 787, 790 (2d Cir. 1994). Moreover, the Court may rely on the plaintiff’s opposition papers as well as the complaint in assessing the legal sufficiency of his claims. See Crum v. Dodrill, 562 F. Supp. 2d 366, 373 n.13 (N.D.N.Y. 2008) (citing Gadson v. Goord, No. 96 Civ. 7544 (SS), 1997 WL 714878, at *1, n.2 (S.D.N.Y. Nov. 17, 1997)). The Court also may consider any document attached to the plaintiff’s complaint or incorporated therein by reference. Chambers v. Time Warner, Inc., 282 F.3d 147, 152-53 (2d Cir. 2002). Even when a document is not incorporated by reference, the Court may consider it in connection with a motion to dismiss if the complaint “relies heavily upon its terms and effect.” Id. at 153 (quoting Int’l Audiotext Network, Inc. v. AT&T, 62 F.3d 69, 72 (2d Cir. 1995)).

D. Motion for Reconsideration

The standard for granting a motion for reconsideration “is strict, and reconsideration will generally be denied unless the moving party can point to controlling decisions or data that the court overlooked – matters, in other words, that might reasonably be expected to alter the conclusion reached by the court.” Shrader v. CSX Transp., Inc., 70 F.3d 255, 257 (2d Cir. 1995) (citing Schonberger v. Serchuk, 742 F. Supp. 108, 119 (S.D.N.Y. 1990)). A motion for reconsideration is not “an opportunity to

‘reargue those issues already considered when a party does not like the way the original motion was resolved.’” Am. Hotel Int’l Group Inc. v. One Beacon Ins. Co., No. 01 Civ. 0654 (RCC), 2005 WL 1176122, at *1 (S.D.N.Y. May 18, 2005) (quoting In re Houbigant, Inc., 914 F. Supp. 997, 1001 (S.D.N.Y. 1996)). An abiding conviction that the issue was wrongly decided therefore is not enough to warrant reconsideration; rather, the issue must have been wrongly decided because the court overlooked important decisions or facts. See id. at *2.

III. Coleman’s Claims

A. Due Process Claims

In his complaint, Coleman challenges the constitutionality of the AOT program. Specifically, he alleges that he was “forced to take medication and attend a program.” (Compl. ¶ III(C)). He further alleges that “Due Process was not followed correctly” because there was no jury, and because he “was not tempor[arily] insane nor had he done anything to anyone or himself; and was not incapacitated.” (Id. ¶ II(B), Attach. ¶ 3(1)). These allegations, liberally construed, can be read to assert that Section 9.60: (a) violates the Due Process Clause of the New York State Constitution; (b) violates Coleman’s substantive and procedural due process rights under the Fourteenth Amendment to the United States Constitution; and (c) violates due process as applied to him.

1. New York Constitutional Claim

In In re K.L., 1 N.Y.3d 362 (2004), the New York Court of Appeals concluded that Section 9.60 does not violate a patient's due process rights. In the course of doing so, the Court of Appeals distinguished AOT from the forcible administration of antipsychotic medications to persons involuntarily committed to inpatient psychiatric facilities, which procedure it previously had concluded, in Rivers v. Katz, 67 N.Y.2d 485 (1986), was lawful in certain limited circumstances. See id. at 369. It therefore is useful to begin consideration of Coleman's due process rights under the New York Constitution with a discussion of Rivers.

In Rivers, several patients involuntarily committed to the Harlem Valley Psychiatric Center pursuant to an order of the Dutchess County Court sought a declaratory judgment that they could not be forced to take antipsychotic drugs against their wishes. 67 N.Y.2d at 491. The court recognized that New York law accorded every adult of "sound mind" the "right to determine what shall be done with his own body . . . and to control the course of his medical treatment." Id. at 492 (citations omitted). Nevertheless, the court identified two circumstances in which the fundamental right to reject treatment must yield to the state's interest. First, when a patient "presents a danger to himself or other members of society . . . , the State may be warranted, in the exercise of its police power, in administering antipsychotic medication over the patient's objections." Id. at 495. The court cautioned that the interests of the state must be compelling, and that

the police power would justify forcibly administering medication only temporarily, while the emergency persisted. Id. at 496.

Second, the court held that the forced administration of medical treatment may be justified when the state exercises its parens patriae powers to care for individuals who are unable to care adequately for themselves due to mental illness. Id. (citing Addington v. Texas, 441 U.S. 418, 426 (1979)). Nonetheless, the court rejected a broad view of that power, emphasizing that it may be invoked only when an individual is “incapable of making a competent decision concerning treatment on his own.” Id. (quoting Rogers v. Okin, 634 F.2d 650, 657 (1st Cir. 1980)). As the court explained, “there is considerable authority within the psychiatric community that from a medical point of view no relationship necessarily exists between the need for commitment and the capacity to make treatment decisions since the presence of mental illness does not ipso facto warrant a finding of incompetency.” Id. at 495. Consequently, “many patients, despite their mental illness are capable of making rational and knowledgeable decisions about [their] medications.” Id. The court held that for the state to administer treatment forcibly when the police power is not implicated, the state therefore must show by clear and convincing evidence that the individual is incapable of making a treatment decision. Id. at 497.

Nearly twenty years later in In re K.L., the Court of Appeals distinguished the forced administration of drugs to inpatients from AOT. The court reasoned that,

unlike the program at issue in Rivers, Section 9.60 “neither authorizes forcible medical treatment in the first instance nor permits it as a consequence of noncompliance with court-ordered AOT.” In re K.L., 1 N.Y.2d at 369. In the court’s view, the only consequence of noncompliance with AOT is that a person may be committed for up to seventy-two hours while a physician evaluates whether he needs to be institutionalized. See id. at n.2. The court further held that it was not violative of due process for law enforcement officers to seize a noncompliant individual and take him to a hospital for that purpose. Id. at 372-73.

The court concluded that “the coercive force of the [AOT] order lies solely in the compulsion generally felt by law-abiding citizens to comply with court directives.” Id. at 370. As a consequence, the court held that the “minimal restriction on the right to refuse treatment” inherent in an AOT order was justified by “the state’s compelling interests in both its police and parens patriae powers.” Id. at 371.

Therefore, to the extent that Coleman challenges the constitutionality of Section 9.60 under the New York State Constitution, his claim is clearly precluded by the Court of Appeals decision in In re K.L.

2. Federal Constitutional Claim

The City notes in its papers that Section 9.60 recently has withstood rational basis scrutiny in federal court. (See City Mem. at 13). While that is true, in the case cited by the City, Mental Disability Law Clinic v. Hogan, 2008 WL 4104460 (E.D.N.Y. Aug.

28, 2008), the late Judge Sifton was considering an equal protection challenge to the statute, not a due process challenge.⁷ Moreover, the plaintiffs were arguing for greater use of AOT, contending that the limitations in Section 9.60 on those eligible for outpatient commitment resulted in the “unnecessary loss of physical liberty for many individuals.” Id. at *12. Consequently, this decision adds nothing to a discussion of Coleman’s due process rights under the United States Constitution.

Although courts have considered programs requiring the involuntary administration of medication to inpatients, no federal court has addressed whether Section 9.60 – or any other state’s AOT program – comports with the Fourteenth Amendment due process rights of those who are ordered to participate.⁸ It nevertheless is clear that the

⁷ The plaintiffs also alleged that Section 9.60 violated the Americans With Disabilities Act. Id. at *1.

⁸ It bears mention that New York is one of over 40 states with some type of AOT program. See Samuel Jan Brakel & John M. Davis, Overriding Mental Health Treatment Refusals: How Much Process is “Due”?, 52 St. Louis U. L.J. 501, 578 (2008). Of these states, however, only thirteen specify different criteria for inpatient and outpatient treatment. See Steven Strang, Assisted Outpatient Treatment In Ohio: Is Jason’s Law Life-Saving Legislation or a Rash Response?, 19 Health Matrix 247, 252 (2009); see also Illissa L. Watnik, A Constitutional Analysis of Kendra’s Law: New York’s Solution for Treatment of the Chronically Mentally Ill, 149 U. Pa. L. Rev. 1181, 1191 (2001).

Of the thirteen states with different outpatient standards, most require a finding of either incompetency or that the individual is an imminent danger to himself or others, standards which are common in inpatient commitment statutes. See, e.g., Ala. Code § 22-52-10.2 (“unable to make a rational and informed decision”); Tex. Health & Safety Code Ann. § 574.034(b) (requiring “severe . . . distress,” inability “to live safely in the community,” and inability to participate voluntarily, each of which must be proved by a recent “overt act”); Va. Code Ann. § 37.2-817 (requiring either substantial likelihood of serious physical harm in the near future or incapacity). Very few states use a standard that reaches a substantially broader group of individuals than that used for inpatient commitment. Watnick, supra, at 1192.

question presents “both substantive and procedural aspects.” See Mills v. Rogers, 457 U.S. 291, 299 (1982). The substantive issue requires the Court to define the protected interest and identify the interests that might outweigh it. Id. The procedural issue relates to “the minimum procedures required by the Constitution for determining that the individual’s liberty interest actually is outweighed in a particular instance.” Id. As set forth below, courts typically have considered such issues in the context of programs involving the forced medication of patients who are incarcerated or involuntarily civilly committed. As these cases indicate, Coleman has not plausibly alleged that his involvement in AOT violated either his substantive or his procedural rights under the Due Process Clause of the Fourteenth Amendment.

a. Substantive Due Process

i. Criminal Law Cases

In Washington v. Harper, 494 U.S. 210, 221-22 (1990), the Supreme Court unequivocally held that an inmate has a “significant liberty interest in avoiding the unwanted administration of antipsychotic drugs under the Due Process Clause of the Fourteenth Amendment.” The Court nevertheless rejected the inmate’s suggestion that he could not be compelled to take such drugs unless “the factfinder makes a substituted judgment that he, if competent, would consent to drug treatment.” Id. at 222. Instead, the Court held that the forcible administration of antipsychotic drugs is permissible in a prison environment “if the inmate is dangerous to himself or others and the treatment is in

the inmate's medical interest." Id. at 227. At the same time, the Court acknowledged that the use of these drugs could have "serious, even fatal side effects," including acute dystonia (a severe involuntary spasm of the upper body), tardive dyskinesia (a potentially irreversible disorder characterized by involuntary, uncontrollable movements of various muscles), swelling of the brain, catatonic states, hypertension, nausea, vomiting, loss of appetite, dry mouth, impotency, and blurred vision. Id. at 229-30 (majority opinion), 239 (Blackmun, J., concurring).

Subsequently, in Riggins v. Nevada, 504 U.S. 127 (1992), a defendant convicted after his insanity defense failed sought review of his conviction on the theory that he should have been allowed to forgo continued medication for the duration of his trial so that he could show the jurors his "true mental state." Id. at 130. Although the trial judge required that the medication be continued, his order failed to explain his reasoning. Id. at 131. Applying Harper, the Supreme Court held that requiring involuntary medication might have been justified if it was medically appropriate and, "considering less intrusive alternatives, essential for the sake of Riggins' own safety or the safety of others." Id. at 135. The Court also suggested that the State could have justified involuntary treatment "by establishing that it could not obtain an adjudication of Riggins' guilt or innocence by using less intrusive means." Id. In the absence of any findings that might support either basis for forced medication, the Court reversed the conviction. Id. at 138.

In Sell v. United States, 539 U.S. 166 (2003), a pretrial detainee sought to overturn an order requiring that he be forcibly medicated in an effort to render him competent to stand trial. The Supreme Court held that “only an ‘essential’ or ‘overriding’ state interest” could overcome an individual’s constitutionally-protected interest in avoiding forced medication. Id. at 178-79. Consequently, it is only in “rare” instances, where the “treatment is medically appropriate, is substantially unlikely to have side effects that may undermine the fairness of the trial, and, taking account of less intrusive alternatives, is necessary . . . to further important governmental trial-related interests, that a person may be medicated so that he can be tried.” Id. at 179. Significantly, the Court suggested that before seeking to justify forced medication on these bases, a court should determine whether it is warranted for a “different purpose, such as the purposes set out in Harper related to the individual’s dangerousness, or . . . where refusal to take drugs puts his health gravely at risk.” Id. at 181-82.

ii. Cases Involving Civilly-Committed Plaintiffs

Since Harper, a few courts have applied the dangerousness standard in the face of substantive due process challenges by civilly-committed patients who were involuntarily medicated. The earliest such decision is Cochran v. Dysart, 965 F.2d 649 (8th Cir. 1992). There, a federal prisoner held beyond the expiration of his sentence by reason of mental defect challenged both his continued commitment and the forced administration of psychotropic drugs. Id. at 649. The record contained a report by a

reviewing psychiatrist who approved the medication because the treating psychiatrist considered the plaintiff “dangerous to himself and others without medication,” although the treating psychiatrist also noted that the plaintiff, when properly medicated, was “able to function [in] open population.” Id. at 650. The report further opined that the plaintiff’s paranoid schizophrenia was a condition that would “respond to treatment with neuroleptic medication [which would] eventually help [him] improve his reality testing.” Id. Concluding that any justification for forced medication other than dangerousness might not pass muster under Harper, the Eighth Circuit remanded the case, instructing the district court to obtain and review the underlying documents on which the reviewing psychiatrist relied. Id. at 651. Subsequently, in Morgan v. Rabun, 128 F.3d 694, 697 (8th Cir. 1997), the Eighth Circuit again applied the Harper standard to a civilly-committed patient because “governmental interests in running a state mental hospital are similar in material aspects to that of running a prison.”

In Preston v. Gutierrez, No. 90-6029-CV-SJ-6, 1993 WL 280819 (W.D. Mo. Jul 23, 1993), a plaintiff was committed to the custody of the Missouri Department of Mental Health after pleading not guilty to a criminal charge by reason of mental defect. Id. at *1. Relying on Cochran and an earlier Eighth Circuit case, United States v. Watson, 893 F.2d 970 (8th Cir. 1990), the court held that the Due Process Clause of the Fourteenth Amendment “requires that officials exercise more than just professional judgment when involuntarily medicating involuntary mental patients[;] they must exercise professional

judgment that the medication is necessary to insure the safety of the patient or others.”

Preston, 1993 WL 280819, at *11. Accordingly, the court invalidated the applicable Missouri policy to the extent that it did not require such a finding.

Hightower by Dahler v. Olmstead, 959 F. Supp. 1549, 1562 (N.D. Ga. 1996), involved a challenge to the involuntary administration of antipsychotic drugs to persons who were hospitalized in accordance with Georgia law because they presented a “substantial risk of imminent harm” to themselves or others, or were “so unable” to care for their own “physical health and safety as to create an imminently life endangering crisis.” Id. at 1553. Balancing the state’s parens patriae and police power interests against the patient’s liberty interest in avoiding forced medication, the court concluded that the Georgia procedures comported with the requirements of substantive due process. Id. at 1562. In reaching this determination, the court noted that permitting the members of the plaintiff class to refuse antipsychotic drugs might lead to the infringement of the constitutional rights of others, including staff members and other patients. Id. The court also relied upon the plaintiffs’ failure to show that there were more appropriate means to accomplish the state’s interests. Id.

Finally, in Jurasek v. Utah State Hospital, 158 F.3d 506, 511 (10th Cir. 1998), the Tenth Circuit considered a state hospital policy authorizing the forced medication of a civilly-committed mental patient if the patient was “gravely disabled” or posed a threat of serious physical harm to himself or others or their property. Id. at 509.

A gravely disabled patient was defined as one who is “in danger of serious physical harm” or who manifests (or will manifest) “severe deterioration in routine function” relative to cognitive or volitional control. Id. at 511. The court rejected the view that Harper should be limited to a prison context, noting that Riggins had applied the same standard to a pretrial detainee. The court further concluded that a patient who is in danger of serious physical harm and is not receiving care essential to mitigate that risk “is, by definition, in need of treatment for the sake of [his or her] own safety.” Id. at 512 (citation and internal quotation marks omitted); see also Graves v. Mid-Hudson, No. CV-04-3957 (FB) (LB), 2006 WL 3103293, at *4 (E.D.N.Y. Nov. 2, 2006) (noting agreement with Jurasek).

iii. Application to Section 9.60

As the Supreme Court recognized in Harper, Riggins, and Sell, Coleman unquestionably has a liberty interest in avoiding the forced administration of antipsychotics. Moreover, only an “essential” interest on the part of the state can override that liberty interest. Sell, 539 U.S. at 178-79.

While Section 9.60 does not expressly state that outpatients must be a danger to themselves or the community before they can be ordered to participate in AOT, the statute requires a finding by the MHP that they are “unlikely to survive safely in the community” without AOT, and that they have a history of noncompliance with mental health treatment that has within the past several years resulted either in hospitalization or

violent behavior toward themselves or others, or the threatened or attempted infliction of serious physical harm on themselves or others. MHL § 9.60(c). The statute also requires that the MHP find, before permitting AOT, that the patients are unlikely to participate voluntarily in outpatient treatments that “would enable [them] to live safely in the community” and that AOT is necessary to “prevent a relapse or deterioration which would be likely to result in serious harm to [themselves] or others.”⁹ *Id.* § 9.60(c)(5), (6) (emphasis added).

Section 9.60 therefore essentially requires a finding of dangerousness – either to the patient or others – before a New York court can require someone to participate in AOT. Section 9.60 further requires the state court to find that the patient is “likely to benefit from [AOT].” *Id.* at 9.60(c)(7). The showing required by the statute consequently is fully consistent with Harper and its progeny.

Moreover, the limitations on a patient’s liberty interests effected by an AOT order are considerably less invasive than those considered in Harper, Riggins, and Sell. As the New York Court of Appeals recognized, Section 9.60 authorizes the MHP to order AOT patients to take antipsychotic medication, and they may face consequences if they do not comply. Unlike the statutes considered in prior cases, however, Section 9.60 does

⁹ The MHL defines “likely to result in serious harm” to mean: “(a) a substantial risk of physical harm to the person as manifested by threats of or attempts at suicide or serious bodily harm or other conduct demonstrating that the person is dangerous to himself or herself, or (b) a substantial risk of physical harm to other persons as manifested by homicidal or other violent behavior by which others are placed in reasonable fear of serious physical harm.” *Id.* § 9.01.

not allow AOT patients to be forcibly injected with medications against their will.¹⁰

Additionally, participation in AOT enables individuals who are at high risk of involuntary hospitalization to remain in the community as outpatients, an alternative which is far preferable, as the plaintiffs in Hogan recognized.

In sum, although Coleman concededly has a liberty interest in avoiding the forced administration of medication, Section 9.60 furthers important government interests, requires medication only where medically appropriate, and is less intrusive than alternative methods of ensuring the safety of the community and mentally ill patients. It follows that the state court, the City, and Bellevue did not violate Coleman's substantive due process rights under the Fourteenth Amendment by requiring participation in AOT.

b. Procedural Due Process

In his complaint, Coleman also claims that "[d]ue [p]rocess was not followed correctly" and that his case was impermissibly heard by the MHP without a jury. (Compl. ¶¶ II(B), III(C)). This language, liberally construed, is sufficient to allege a procedural due process claim under the Fourteenth Amendment.

To establish such a claim, a plaintiff first must show that he was deprived of a liberty or property interest. See Bd. of Regents of State Colleges v. Roth, 408 U.S. 564, 571 (1972); Finley v. Giacobbe, 79 F.3d 1285, 1296 (2d Cir. 1996). If such a deprivation

¹⁰ Admittedly, the likely practical consequence of a refusal to submit to AOT would be involuntary commitment, assuming an individual meets the criteria in MHL § 9.01. Once the person is committed, the hospital would of course have to abide by the more stringent criteria laid out in Rivers v. Katz if it wished to compel forcible medication.

occurred, the Court then must consider what process was due and whether it was provided. See Matthews v. Eldridge, 424 U.S. 319, 333-34 (1976).

As noted above, there is no question that Coleman had a constitutionally-protected liberty interest in not being forcibly medicated with psychotropic drugs against his will. Sell, 539 U.S. at 178; Riggins, 504 U.S. at 134-35; Harper, 494 U.S. at 221-22. Accordingly, the principal issue before this Court is whether Section 9.60 afforded Coleman adequate procedural protections. If so, the Court also must consider whether those procedural protections, in fact, were made available to him. See Project Release v. Prevost, 722 F.2d 960, 970 (2d Cir. 1983).

In Project Release, the Second Circuit considered these issues in the context of a different provision of the MHL permitting the forced administration of antipsychotic medication to civilly-committed inpatients prior to a judicial commitment hearing. The plaintiffs argued that the nonconsensual administration of such drugs in those circumstances violated their “liberty interest in personal and bodily integrity” and diminished their ability to “participate effectively” in hearings. Id. at 977. The case came before the Court of Appeals after the district court granted partial summary judgment to the state defendants with respect to the claims of a plaintiff initially admitted as an inpatient on an emergency basis (under MHL § 9.39), later converted to a voluntary inpatient (under MHL § 9.13), and eventually held involuntarily (under MHL § 9.27) after she sought to leave the hospital. Id. at 964.

Under New York regulations, different standards apply to each type of patient. See N.Y. Comp. Codes R. & Regs. tit. 14, § 27.8. Thus, patients who are committed voluntarily or on an emergency basis may be given antipsychotic drugs over their objection only in emergency situations where “treatment appears necessary to avoid serious harm to life or limb of the patients themselves.” Id. § 27.8(b)(1). Involuntarily-committed patients may not be medicated over their objection unless the head of service approves and, in the event of an appeal, the facility director concurs that treatment is warranted. Id. § 27.8(b)(3), (c). A patient who is committed voluntarily has no right to appeal, however, because the facility director may discharge him with a recommendation for outpatient treatment or, if appropriate, take the steps necessary to pursue involuntary commitment under MHL § 9.27. Id. § 27.8(b)(2).

Although Project Release was decided before Harper, the Second Circuit correctly prognosticated that the Supreme Court would find that patients had a liberty interest in refusing antipsychotic medications. Project Release, 722 F.2d at 979. The court found it unnecessary to resolve that issue, however, because “such an interest can be created as a matter of state law, and the New York regulations established that right.” Id.

Turning to the question “whether an involuntarily committed mental patient’s right to refuse treatment with antipsychotic medication is sufficiently protected by New York State procedures,” the Second Circuit concluded that to be adequate those procedures “must at least provide sufficient opportunity for professional input.” Id. at

917-80. Since the relevant New York regulations provided for several levels of review by medical personnel, see id. at 980 (citing N.Y. Comp. Codes R. & Regs. tit. 14, §§ 27.8, 27.9), the court denied relief. Id. at 980-81. The court also rejected the plaintiffs' suggestion that prior judicial review was required, stating that "due process requires an opportunity for hearing and review of a decision to administer antipsychotic medication – but such a hearing need not be judicial in nature." Id. at 981 (emphasis added).

Section 9.60 plainly provides for medical input before any AOT order is issued. Indeed, a petition seeking AOT must be supported by the affirmation or affidavit of a physician who either has examined the patient or certifies that he or his designee were unable to persuade the patient to submit to an examination. MHL § 9.60(e)(i)-(ii). Additionally, the state court cannot direct AOT unless a physician who has personally examined the patient testifies at the hearing. Id. § 9.60(h)(2). During that testimony, the physician must provide extensive detail supporting the petitioner's application and establish that AOT is "the least restrictive alternative." Id. § 9.60(h)(4).¹¹ As noted previously, if the patient declines to submit to a medical examination, the statute provides a means for the patient to be forcibly taken to a hospital for that purpose. See id. § 9.60(h)(3).

In light of these extensive procedural protections, which not only require professional input, but permit patients to challenge the medical testimony proffered by the

¹¹ Section 9.60 also entitles the patient to be represented at the hearing by the Mental Hygiene Legal Service and to participate fully in the hearing. Id. § 9.60(g), (h)(5).

petitioner and adduce additional evidence of their own, Coleman cannot seriously contend that Section 9.60 fails to require adequate professional input before an AOT order is issued by the MHP. Moreover, Section 9.60 expressly requires that a judicial hearing be held before such an order issues and permits a patient to seek review before a second justice of the New York Supreme Court and a jury. Accordingly, even if due process requires the involvement of a court before a patient is directed to comply with AOT – which it does not – Section 9.60 plainly comports with that requirement.

In his complaint, Coleman nevertheless alleges that his case “was heard and judged without a jury.” (Compl. ¶ III(C)). However, Section 9.60 permits a patient (or his relative or friend) to seek judicial review by petitioning a justice of the Supreme Court other than the one who issued the AOT order. Moreover, if such a petition is filed, the justice receiving it must “cause a jury to be summoned” so that the issue can be tried, unless a jury is waived. MHL §§ 9.35, 9.60(m). Coleman therefore had the opportunity to have his objections to AOT presented to a jury. Nowhere in his papers does he indicate that either he or his representative ever requested a rehearing before a different justice, much less that a jury be summoned. In the absence of such a request, the mere fact that the orders issued by the MHP were not reviewed elsewhere in the state court system does not give rise to a procedural due process violation.

The procedures set forth in Section 9.60 therefore are adequate to withstand a facial due process challenge under the Fourteenth Amendment. Moreover, Coleman has

not alleged any facts which indicate that those procedures either were unavailable to him or were misapplied.¹² Cf. Project Release, 722 F.2d at 970 (noting that the case seems “to be illustrative of the application of the statute, rather than its misapplication”). It follows that both the MHP and the City are entitled to the dismissal of Coleman’s claims against them.¹³

B. FDA

In his complaint, Coleman alleges that the FDA is liable for money damages for “putting such harmful medication on [the] medicine market. (Compl. ¶ V). He further claims that there is sufficient evidence of the side effects of the medicines that were part of his AOT plan to require that they be taken off the market and that “it is

¹² In his complaint, Coleman does allege that “[t]reatment still continues by force without Supreme Court ruling.” (Compl. Attach. ¶ 3(1)). This statement, however, is wholly conclusory and simply not plausible in light of the records submitted by the City, which confirm that Coleman graduated from the AOT program in early 2009. See Twombly, 550 U.S. at 555-56.

¹³ By letter dated February 15, 2010, Coleman seeks an extension of time to serve the MHP, which was not served within the 120-day period required by Rule 4(m) of the Federal Rules of Civil Procedure. This application should be denied for at least four reasons. First, Coleman has not shown good cause for the delay, as Rule 4(m) requires. Second, even if the MHP had been served, Coleman’s claims against it would have to be dismissed because, as shown above, he has not pleaded a plausible due process claim for which it could be liable. Third, even if Coleman could show that the MHP violated his rights, a judicial arm of the state is not a “person” subject to suit under 42 U.S.C. § 1983. See Zuckerman v. App. Div., Second Dep’t, Supreme Court of State of N.Y., 421 F.2d 625, 626 (2d Cir. 1970). Finally, even if the MHP were a “person” subject to suit in a civil rights action, the court clearly acted within the scope of its judicial functions and therefore would be entitled to judicial immunity. See, e.g., Pierson v. Ray, 386 U.S. 547, 553-54 (1967) (“Few doctrines were more solidly established at common law than the immunity of judges from liability for damages for acts committed within their judicial jurisdiction.”); Peker v. Steglich, 324 F. App’x 38, 39 (2d Cir. 2009) (“Under New York State law, judges are absolutely immune for acts undertaken in performance of their judicial function.”).

negligent not to do such.” (See Docket No. 46) (Affirm. in Opp’n to FDA’s Mot. to Dismiss, dated June 24, 2009).

Although Coleman contends that he has the “right to bring a lawsuit [] against anyone federal or otherwise in [f]ederal [c]ourt,” (see id.), the law says no such thing. Rather, to bring an action against a federal agency, such as the FDA, Coleman first must establish a basis for overcoming sovereign immunity. United States v. Mitchell, 445 U.S. 535, 538 (1980). This requires him to show that the United States has “unequivocally” expressed in a statute its willingness to be sued. Lane v. Pena, 518 U.S. 187, 192 (1996); United States v. Shaw, 309 U.S. 495, 500-01 (1940). Here, Coleman might intend to rely upon either of two statutes: the Federal Food, Drug, and Cosmetic Act (“FDCA”) and the Federal Tort Claims Act (“FTCA”). On the facts of this case, neither permits Coleman to sue the FDA.

1. FDCA

The FDCA “comprehensively regulates the introduction of new drugs into interstate commerce.” In re Zyprexa Prods. Liab. Litigation, No. 04 MDL 1596, 2007 WL 2332544, at *1 (E.D.N.Y. Aug. 15, 2007); see Vermont v. Leavitt, 405 F. Supp. 2d 466, 473 (D. Vt. 2005) (“The FDCA creates a ‘closed’ system in which the FDA regulates the manufacture, marketing and labeling of drugs sold in the United States.”). Under the FDCA, however, there is no private right of action. See 21 U.S.C. § 337(a) (“all such proceedings for the enforcement, or to restrain violations, of this chapter shall

be by and in the name of the United States”); PDK Labs, Inc. v. Friedlander, 103 F.3d 1105, 1113 (2d Cir. 1997). The FDCA consequently does not provide a basis for Coleman to pursue claims against the FDA in this suit.

2. FTCA

The FTCA authorizes civil actions for monetary damages to be brought when “personal injury or death [is] caused by the negligent or wrongful act or omission of any employee of the Government while acting within the scope of his office or employment” and the circumstances are such that the United States would be liable if it were a private party. 28 U.S.C. § 1346(b)(1). Because the FDA’s actions in regulating pharmaceuticals are not of the type that a private party could undertake, the FTCA does not authorize the claims that Coleman seeks to bring against the FDA. See, e.g., Dorking Genetics v. United States, 76 F.3d 1261, 1266 (2d Cir. 1996) (FTCA is inapplicable to direct violations of statutes by the government); C.P. Chem. Co. v. United States, 810 F.2d 34, 37-38 (2d Cir. 1987) (“[Q]uasi-legislative or quasi-adjudicative action by an agency of the federal government is action of the type that private persons could not engage in and hence could not be liable for under local law.”).

Consequently, because Congress has not subjected the FDA to lawsuits under the FDCA or FTCA, Coleman’s claims against that agency must be dismissed for lack of subject matter jurisdiction. See United States v. Sherwood, 312 U.S. 584, 586-87

(1941); Williams v. United States, 947 F.2d 37, 39 (2d Cir. 1991); F.D.I.C. v. Meyer, 510 U.S. 471, 477 (1994).

C. Lilly and Ortho

Lilly and Ortho manufacture the drugs that Coleman was prescribed. In his complaint, Coleman sets forth a litany of adverse reactions that he and others allegedly have suffered as a consequence of taking Haldol and Risperdal (manufactured by Ortho) and Zyprexa (manufactured by Lilly). (See Compl. ¶¶ III(C), IV & Attach. ¶ 3). The adverse reactions that he claims to have experienced include heart problems, nausea, weight gain, hearing voices, and difficulty concentrating and sleeping. Coleman contends that he did not have any of these difficulties until he began AOT, and that the manufacturer's drugs therefore should not be on the market. (See id.). Liberally construed, his complaint seeks to state product liability claims against Ortho and Lilly based on their alleged failure to provide him with adequate warnings.

The Second Circuit has summarized the law of New York applicable to such claims as follows:

[A] drug manufacturer, like any other manufacturer, can be held liable for a defective product under the theory of strict products liability. Unlike most other products, however, ethical or prescription drugs may cause untoward side effects despite the fact that they have been carefully and properly manufactured. For purposes of strict products liability, these drugs, aptly described as “[u]navoidably unsafe products[,]” are not deemed defective or unreasonably dangerous so long as they are accompanied by proper directions for use and adequate warnings as to potential side effects.

Lindsay v. Ortho Pharm. Co., 637 F.2d 87, 90 (2d Cir. 1980) (citation and internal parentheses omitted). A plaintiff who seeks to recover against a drug manufacturer on a products liability theory also “must prove that the drug caused her injury and that the manufacturer breached a duty to warn of the possibility that the injurious reaction might occur.” Id. at 90-91.

Assuming that Coleman suffered each of the adverse reactions he describes, to state a claim on a failure-to-warn theory he still must show that Ortho or Lilly failed to provide adequate warnings of these potential side effects of their drugs. The manufacturer’s duty, however, is “to warn the doctor, not the patient.” Id. at 91. As the Second Circuit has explained, the “doctor acts as an ‘informed intermediary’ between the manufacturer and the patient, evaluating the patient’s needs, assessing the risks and benefits of available drugs, prescribing one, and supervising its use.” Id.

In assessing the adequacy of the warnings given, the Court can take judicial notice of the description of pharmaceutical drugs in the Physicians’ Desk Reference (“PDR”). See, e.g., Ariola v. Onondaga County Sheriff’s Dep’t, 2007 WL 119453, at *7 n.61 (N.D.N.Y. Jan. 10, 2007). As the PDR establishes, well prior to the advent of Coleman’s AOT, each of the side effects he claims to have suffered was fully disclosed to physicians. For example, the 2001 edition of the PDR disclosed that Risperdal may cause “orthostatic hypotension associated with dizziness, tachycardia, and in some patients,

syncope,”¹⁴ “somnolence,” “impair[ed] judgment, thinking or motor skills,” and that premarketing assessments further indicated a risk of increased dream activity, diminished sexual desire and erectile dysfunction, nervousness, diarrhea, and fatigue. Physicians’ Desk Reference, 1580-83 (55th ed. 2001).

The 2001 PDR further discloses that Haldol may cause “Parkinson-like symptoms,” insomnia, restlessness, anxiety, agitation, drowsiness, confusion, grand mal seizures, catatonic-like behavioral states, diarrhea, vomiting, nausea, and numerous heart problems. Id. at 2334-36. Indeed, the 2001 PDR states that “[c]ases of sudden and unexpected death have been reported in association with the administration of [Haldol].” Id. at 2336.

The 2001 PDR entry for Zyprexa cautions physicians about the risk of irregular pulse or blood pressure, dizziness, tachycardia, syncope, somnolence, and impaired thinking. Id. at 1788-93.

In view of these extensive warnings, Coleman cannot plausibly allege that his treating physicians were not cautioned about the side effects of the Ortho and Lilly drugs about which he complains. Indeed, on each occasion that the MHP ordered that Coleman submit to AOT, the physician’s treatment plan submitted in support of the petition specifically noted that Coleman’s potential adverse side effects might include

¹⁴ Orthostatic hypotension is a “form of low blood pressure that occurs in a standing position.” Stedman’s Medical Dictionary, (27th Ed. 2000). Syncope is a “loss of consciousness and postural tone caused by diminished cerebral blood flow.” Id.

anticholinergic effects,¹⁵ extrapyramidal effects,¹⁶ tardive dyskinesia,¹⁷ sedation, weight gain, and orthostatic hypotension. (See Hui Decl. I Exs. A-E).

Any conceivable doubt in this regard is dispelled by Coleman's opposition papers, which concede that the "doctors that were in care of [him] knew the side effects of [the] medication discussed in this case." (Docket No. 52 (Coleman Affirm. in Opp'n to Ortho Mot.) at 1). The fact that Coleman himself was not warned, even if established, does not entitle him to proceed against Ortho or Lilly in light of the "informed intermediary" rule and the undisputed fact that his physicians were fully aware of the many possible side effects of the antipsychotic drugs they prescribed for him.

D. Bellevue and St. Luke's

Liberally construed, Coleman's complaint alleges a state law claim that Bellevue and St. Luke's (or their doctors) committed malpractice by failing to secure his informed consent before medicating him with psychotropic drugs. In New York, this

¹⁵ An anticholinergic effect is one that is antagonistic to the passage of impulses through the parasympathetic or other cholinergic nerve fibers. Stedman's.

¹⁶ Extrapyramidal side effects include tremor, akathisia (movement disorders characterized by inner restlessness and the inability to sit or stand still), slurred speech, dystonia (involuntary muscle contractions which sometimes are painful), bradyphrenia (slowing of thought processes), bradykinesia (slowing of movement), and muscular rigidity. See Extrapyramidal Side Effects, http://bipolar.about.com/od/glossary/g/gl_extrapyramid.htm (last visited Feb. 24, 2010).

¹⁷ Tardive dyskinesia may result in "involuntary repetitive tic-like movements . . . primarily in the facial muscles or (less commonly) the limbs, fingers and toes. The hips and torso may also be affected." See Tardive Dyskinesia Introduction and Overview, <http://www.tardivedyskinesia.com> (last visited Feb. 24, 2010); see also Harper, 494 U.S. at 230.

cause of action is statutorily defined. See N.Y. Pub. Health Law § 2805-d. Accordingly, Coleman must establish “the failure of the person providing the professional treatment . . . to disclose . . . alternatives thereto and the reasonably foreseeable risks and benefits involved as a reasonable medical . . . practitioner under similar circumstances would have disclosed, in a manner permitting the patient to make a knowledgeable evaluation. Id. § 2805-d(1). Coleman also must show “that a reasonably prudent person in [his] position would not have undergone the treatment or diagnosis if he had been fully informed and that the lack of informed consent is a proximate cause of the injury or condition for which recovery is sought.” Id. at § 2805-d(3). The cause of action further is limited to non-emergency cases. Id. at § 2805-d(2).

A federal court may exercise supplemental jurisdiction over such a state law claim when a federal claim vests the court with subject matter jurisdiction and the state and federal claims “derive from a common nucleus of operative fact.” United Mine Workers of Am. v. Gibbs, 383 U.S. 715, 725 (1966). A federal court also has the discretion to retain a pendent state claim after dismissing a plaintiff’s federal claims on the merits prior to trial, but it must consider “the values of judicial economy, convenience, fairness, and comity in order to decide whether to exercise jurisdiction.” Carnegie-Mellon Univ. v. Cohill, 484 U.S. 343, 350 (1988); 28 U.S.C. § 1367(c)(3). “[I]n the usual case in which all federal-law claims are eliminated before trial, the balance of factors . . . will point toward declining to exercise jurisdiction over the remaining

state-law claims.” Carnegie-Mellon Univ., 484 U.S. at 350 n.7; see also Klein & Co. Futures, Inc. v. Bd. of Trade of City of N.Y., 464 F.3d 255, 262 (2d Cir. 2006) (“It is well settled that where . . . the federal claims are eliminated in the early stages of litigation, courts should generally decline to exercise pendent jurisdiction over remaining state law claims.”).

Coleman has not shown that there is any reason why the Court should depart from the usual rule in this case. Accordingly, because each of Coleman’s federal claims is subject to dismissal for the reasons set forth above, his state law claims against Bellevue and St. Luke’s should be dismissed without prejudice to his refiling in state court. For the same reason, his motion for reconsideration of this Court’s order denying his request for a default judgment also should be denied.

IV. Conclusion


For the foregoing reasons, the motions of the City (Docket No. 14), the FDA (Docket No. 39), Lilly (Docket No. 42), and Ortho (Docket No. 50), should be granted in full; Bellevue’s motion (Docket No. 36) should be granted insofar as it addresses Coleman’s constitutional claims; Coleman’s motion (Docket No. 48) should be denied; and Coleman’s malpractice claims should be dismissed without prejudice.

Notice of Procedure for Filing of Objections to this Report and Recommendation

The parties shall have fourteen days from the service of this Report and

Recommendation to file written objections pursuant to 28 U.S.C. § 636(b)(1) and Rule 72(b) of the Federal Rules of Civil Procedure. See also Fed. R. Civ. P. 6(a) and (d). Any such objections shall be filed with the Clerk of the Court, with courtesy copies delivered to the chambers of the Honorable Victor Marrero and to the chambers of the undersigned at the United States Courthouse, 500 Pearl Street, New York, New York 10007, and to any opposing parties. See 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 6(a), 6(d), 72(b). Any requests for an extension of time for filing objections must be directed to Judge Marrero. The failure to file these timely objections will result in a waiver of those objections for purposes of appeal. See 28 U.S.C. § 636(b)(1); Fed. R. Civ. P. 6(a), 6(d), 72(b); Thomas v. Arn, 474 U.S. 140 (1985).

Dated: New York, New York
February 25, 2010


FRANK MAAS
United States Magistrate Judge

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